FARNAN LLP

May 8, 2020

VIA E-FILING

The Honorable Colm F. Connolly
J. Caleb Boggs Federal Building
844 N. King Street
Room 4124; Unit 31
Wilmington, DE 19801-3555

[redacted]

RE: *Par Pharmaceutical Inc., et al. v. Eagle Pharmaceuticals Inc.*
C.A. No. 18-cv-823-CFC

Dear Judge Connolly:

Par opposes Eagle's request for leave to file a summary judgment motion.

In Hatch-Waxman cases, "if a product that an ANDA applicant is asking the FDA to approve for sale falls within the scope of an issued patent, a judgment of infringement must necessarily ensue." *Sunovion Pharms., Inc. v. Teva Pharms. USA, Inc.*, 731 F.3d 1271, 1278 (Fed. Cir. 2013). Accordingly, what the generic "has asked the FDA to approve as a regulatory matter is the subject matter that determines whether infringement will occur." *Id.* Promises regarding what the filer will do during manufacturing are irrelevant if FDA approval would permit it to sell products within a broader range. *Id.* Moreover, the analysis does not end with the ANDA specifications; real-world evidence may be brought to bear to determine what the characteristics of the product will be once launched. *See, e.g.*, *Tyco Healthcare Grp. LP v. Mutual Pharm. Co., Inc.*, 762 F.3d 1338, 1344 (Fed. Cir. 2014); *Bayer AG v. Biovail Corp.*, 279 F.3d 1340 (Fed. Cir. 2002).

Biovail is on-point. There, the ANDA specification required that the active ingredient have a "specific surface area" (SSA) above the claimed range. The Federal Circuit reversed summary judgment of non-infringement based on evidence that the active ingredient could meet the ANDA specification initially, but later fall within the claimed range once incorporated into a finished product. Eagle cited to an earlier, related case and tried to distinguish the pertinent ruling in a footnote. But Eagle fails to come to grips with the 60 mg ANDA product at issue in the later decision. The Federal Circuit held that "[e]ven assuming Elan strictly follows its 60 mg ANDA … in making a commercial tablet, Professor Antonietti's declaration raises a legitimate question as to whether Elan will likely make a 60

mg product that literally infringes Bayer's '466 patent upon approval of the ANDA." 279 F.3d at 1346-47.[1]

Here,

and indeed,

Par's Counter-Statement of Fact ("Par-CSOF"), ¶1.

Id., ¶3. As in *Biovail*,

Id., ¶4-5. Accordingly, the commercial sale of products , and the administration of such products to patients , would infringe the Patents-in-Suit. *See* 35 U.S.C. § 271 (it is an act of infringement to make, ***use***, or ***sell*** patented inventions).

[1] *In re Brimonidine Patent Litigation*, is inapposite—the generic's pH release specification was below the claimed range, and "[b]oth parties agree[d] that to the extent the pH of the formulation changes over time, it will fall, not rise." 643 F.3d 1366, 1377 (Fed. Cir. 2011). If anything, the case supports Par—
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As in *Sunovion*, Eagle cannot avoid infringement by 731 F.3d at 1279 ("If it had no intent to infringe, Reddy should not have requested, or should not accept, approval to market a product within the scope of the claim.").

Eagle's second-line defense is that Dr. Kirsch, however, provided an opinion that Par-CSOF, ¶¶6-19. This alone is dispositive on summary judgment.

Moreover, Eagle is well aware there is no anomaly. *Id.*, ¶¶6-13.

Id., ¶8.

Id., ¶7.

Id., ¶6.

Eagle tries to distract the Court from these salient facts by [redacted]

[redacted]

Id., ¶¶10-13. Plainly, there is at least an issue of fact for trial here.

Finally, the Court indicated in the Docket Notice that it would only entertain a motion resolving the entire case. Eagle has not addressed Par's claim under § 271(a), which seeks declaratory relief under traditional patent law principles. At minimum, Par is entitled to a declaration that [redacted] Nor does Eagle commit to dismiss its invalidity and enforceability counterclaims if it prevails.

For all these reasons, this case is a poor candidate for summary judgment briefing.

Respectfully submitted,

/s/ Brian E. Farnan

Brian E. Farnan

cc: Counsel of Record (Via E-Mail)

CERTIFICATION OF COMPLIANCE

The foregoing document complies with the type-volume limitation of the Court's November 6, 2019 Standing Order and April 9, 2020 Oral Order. The text of this document was prepared in Times New Roman, 14 point. According to the word processing system used to prepare it, this document contains 988 words, excluding letterhead, captions, and related non-substantive portions.

/s/ Brian E. Farnan
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Dated: May 8, 2020